LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report

Scientific discussion

Ofloxacin mibe
ofloxacin

SE/H/1285/01/DC

This module reflects the scientific discussion for the approval of Ofloxacin mibe, 3 mg/ml, eye drops, solution. The procedure was finalised at 2014-04-23. For information on changes after this date please refer to the module 'Update'.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se

I. INTRODUCTION

The application for Ofloxacin mibe 3 mg/ml eye drops, solution is a generic application made according to Article 10(3) of Directive 2001/83/EC. The applicant, mibe GmbH Arzneimittel applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and AT, DE and PL.
The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Floxal Augentropfen 3 mg/ml eye drops, solution authorised in DE since 1991, with Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Ofloxacin mibe is presented in the form of eye drops, solution containing 3 mg of ofloxacin per ml solution. The excipients are benzalkonium chloride, hydrochloride acid, sodium chloride, sodium hydroxide and water for injection. The solution is filled in plastic bottles.

II.2 Drug Substance

Ofloxacin has a monograph in the Ph Eur.

Ofloxacin is a pale yellow or bright yellow, crystalline powder, which is slightly soluble in water, soluble in glacial acetic acid, slightly soluble or soluble in methylene chloride and slightly soluble in methanol. The structure of ofloxacin has been adequately proven and its physico-chemical properties sufficiently described. The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The active substance specification includes relevant tests and the limits for impurities/degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies under ICH conditions have been conducted and the data provided are sufficient to confirm the retest period.

II.3 Medicinal Product

Ofloxacin mibe 3 mg/ml eye drops, solution is formulated using excipients described in the current Ph Eur, except for 1N hydrochloric acid and 1M sodium hydroxide which are controlled according to acceptable in house specifications. All raw materials used in the product are of vegetable origin/has demonstrated compliance with Commission Directive 2003/63/EC and the NfG on Minimising the risk of transmitting Animal Spongiform Encephalopathy Agents via human and veterinary medicinal products (EMEA/410/01).

The manufacturing process has been sufficiently described and critical steps identified. Results from the process validation studies confirm that the process is under control and ensure both batch to batch reproducibility and compliance with the product specification.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies under ICH conditions have been performed and data presented support the shelf life claimed in the SPC, when stored below 25°C in the original package in order to protect from light. The shelf life after first opening of the bottle is 4 weeks.

III. NON-CLINICAL ASPECTS

III.1 Discussion on the non-clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to preclinical data, no further such data have been submitted or are considered necessary.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

Since this product has been shown to be essentially similar and refer to a product approved based on a full application, no further pharmacokinetic data have been submitted or no such data are warranted for an eye drop.

IV.2 Discussion on the clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to clinical efficacy/safety data, no further such data have been submitted or are considered necessary.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User consultation
The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.
The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

The risk/benefit ratio is considered positive and Ofloxacin mibe 3 mg/ml eye drops, solution is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Ofloxacin mibe 3 mg/ml eye drops, solution was successfully finalised on 2014-04-23.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report – Update

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
						Y/N (version)

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.mpa.se E-mail: registrator@mpa.se